# Disposable spacers for pressurised metered dose inhalers (pMDIs) – back to the future?

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## Introduction

- Poor pMDI technique led to the development of spacer/chamber devices.
- Use of these devices is recommended internationally in Guidelines.
- Cost, emergency use of pMDIs, and disposal affect availability and adherence to use.
- These aspects have fuelled the development of innovative spacer devices.

Figure 1


## Background

- We revisited the features of self-sourced and readily disposable spacers.
- Ease of use, hygiene and performance-reliability were device requirements.
- A stackable, recyclable device (paper body and interchangeable plastic end-fittings) with intuitive assembly has been developed (**Figures 1 and 2**).
- We report here the initial *in vitro* aerosol performance assessments.

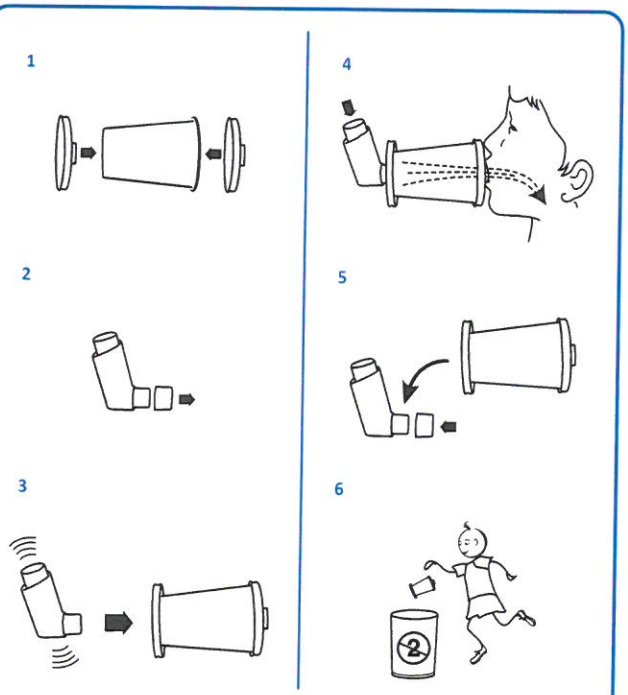


Figure 2

## Objective and Basics

- To assess salbutamol sulphate aerosol characteristics delivered via the new spacer.
- Two separate studies, each using the new DispozABLE™ Spacer.
- All testing and analytical chemistry conducted to GLP at an independent laboratory.
- 8-stage Andersen Cascade Impactor operated at 28 L/min.

## Study 1

- Ventolin® HFA pMDI (GSK), 90µg ex-mouthpiece, 108µg ex-valve.
- Ventolin pMDI alone (n=5) compared with pMDI plus Spacer (n=3).
- Two sets of data collected:
  - conventional pMDI actuation.
  - 1-second delay between actuation and impactor function to mimic sub-optimal use (eg. open-mouth, misaligned device, an emergency).

| **Devices** | **Fine Particle Dose particle size <5µm** (mean µg ± SD) | |
|---|---|---|
| | Optimal use | Sub-optimal use |
| pMDI alone (n=5) | 55.1 ± 4.6 | 10.2 ± 2.2 |
| pMDI + DispozABLE Spacer (n=3) | 56.6 ± 5.7 | 37.7 ± 7.7 |

### Study 1 conclusions

- Mean Fine Particle Dose from optimal use of the pMDI alone and from pMDI plus new spacer were very similar.
- When used sub-optimally, the pMDI plus new spacer performed better than the pMDI, delivering three times the dose.

## Study 2

- Ventolin® HFA and ProAir® HFA (Teva) pMDI, 90µg ex-mouthpiece, 108µg ex-valve.
- Three spacer samples tested on three occasions with each pMDI (18 tests in total).
- ANOVA (F-statistic < 4.74 = no significant difference at 95% confidence level).
- Representative mean ± SD data are given in the table.

| **Aerosol characteristic** (µg/actuation) | **HFA pMDI + DispozABLE Spacer** (3 replicates) | | | |
|---|---|---|---|---|
| | Ventolin | F-statistic | ProAir | F-statistic |
| Total dose delivered | 49.0 ± 4.9 | 0.55 | 48.0 ± 5.1 | 0.60 |
| Total respirable dose (0.5-5.0µm) | 40.7 ± 4.6 | 0.35 | 38.0 ± 4.6 | 0.41 |
| Fine particle dose (<4.7µm) | 41.6 ± 4.3 | 0.27 | 39.0 ± 4.8 | 0.41 |

### Study 2 conclusions

- There were no significant differences between the samples for all aerosol characteristics.
- The data were typical for the pMDI devices tested.

## Conclusions

1. The data indicate that this low-cost, simple-to-use spacer is suitable for effective delivery of medication (salbutamol sulphate).
2. Although use of a conventional spacer is preferable to a home-made device (except where no alternative exists), a developed and tested, low-cost, disposable device may be a preferable, substitute in the home or emergency inhaler tool-kit, and for post challenge test recovery.

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